

REMARKS

In the Office Action of April 9, 2007, the Examiner has divided the claims into four (4) groups: Group I, claims 1-5 (in part) and 7-10 (in part), drawn to a method for preparing a transgenic plant expressing thyroid stimulating hormone receptor (hTSHR); Group II, claims 1-5 (in part) and 7-10 (in part), drawn to a method for preparing a transgenic plant expressing thyroid stimulating hormone receptor extracellular domain (hTSHR-ECD); Group III, claims 6 (in part) and 11-14 (in part), drawn to a transformed plant expressing thyroid stimulating hormone receptor (hTSHR); and Group IV, claims 6 (in part) and 11-14 (in part), drawn to a transformed plant expressing thyroid stimulating hormone receptor extracellular domain (hTSHR-ECD).

Applicants traverse this requirement. Reconsideration and withdrawal thereof are earnestly requested.

The Examiner states that Groups I-IV in the present application are not so linked as to form a single general inventive concept under PCT Rule 13.1 because of the following reasons. The Examiner believes that the technical feature linking Groups I-IV is the expression of a protein comprising the extracellular domain of the TSHR in a plant. However, the Examiner believes that Steins et al. (Biotechnol. Prog. (2000), 16:703-709) disclose a recombinant hTSHR and Whitelam (J. Sci. Food Agric. (1995), 68:1-9) discloses that production of recombinant proteins in plants is a cost-effective and attractive option for industrial and therapeutic biomolecules. Therefore, the Examiner believes that the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined under PCT Rule 13.2 as it allegedly does not define a contribution over the prior art. Applicants respectfully disagree with the Examiner.

Stiens et al. disclose development of serum-free bioreactor production of recombinant human thyroid stimulating hormone receptor to overcome very low expression of functional TSHR in mammalian cells and produce large amounts of hTSHR. Stiens et al. also disclose that expression of TSH-R in bacteria, yeast, or insect cells results in nonfunctional, denaturated receptor. Stiens et al. further disclose development of a serum-free production-scale process based on human leukemia cell line K562. However, nowhere in Stiens et al. discloses or suggests expression of hTSHR in plant as in the presently claimed invention.

Whitelam merely discloses production of recombinant proteins in plants. Whitelam also discusses problems of plant expression system, current status and future prospects for the plant expression of several examples. However, nowhere in Whitelam discloses or suggests expression of hTSHR in plant as in the presently claimed invention.

As discussed above, it is believed that a transformed plant expressing hTSHR or hTHSR-ECD of the presently claimed invention cannot be derived by combining Stiens et al. and Whitelam. Rather, in the absence of examples or suggestions of expressing hTSHR or hTHSR-ECD in plant in Whitelam, it appears that Stiens et al. actually discourage expression of hTSHR or hTHSR-ECD in plants. Therefore, Applicants submit that Groups I-IV in the presently claimed invention share the special technical feature of “a transformed plant expressing hTSHR or hTHSR-ECD” and therefore, it is believed that unity of invention rules under PCT are satisfied.

All of the inventive groups divided by the Restriction Requirement are directed to a method of preparing transformed plants expressing hTSHR or hTSHR-ECD, a transformed plant prepared by the method, and a method of preparing hTSHR or hTSHR-ECD from the transformed plant. Therefore, the claimed transformed plant and the methods are closely related.

Accordingly, all of the claims in Groups I-IV should be considered and examined as a single invention.

Furthermore, Applicants submit that there is not a serious burden placed upon the Examiner to search and consider all of the claims. Applicants submit that there is not a serious burden placed upon the Examiner to search and consider at least Groups I and II together because hTSHR-ECD, which is an extracellular domain of hTSHR, and hTSHR are very closely related to each other.

However, in order to be responsive to the outstanding Restriction Requirement, Applicants provisionally elect to prosecute the subject matter of Group I, claims 1-5 (in part) and 7-10 (in part), drawn to a method for preparing a transgenic plant expressing hTSHR, for prosecution on the merits, with traverse. Applicants specifically preserve the right to prosecute the non-elected claims.

Accordingly, early examination on the merits is respectfully requested.

The Commissioner is hereby authorized to charge JHK Law's Deposit Account No. **502486** for such fees required under 37 CFR §§ 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. **502486**.

May 8, 2007

Respectfully submitted,

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